

United States Court of Appeals

For the First Circuit

No. 24-1917

BERKEY INTERNATIONAL, LLC,

Plaintiff, Appellant,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; DAVID COBB, in
their official capacity; LEE M. ZELDIN,* Administrator; CHRISTINE
TOKARZ, in their official capacity,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

[Hon. Camille L. Vélez-Rivé, U.S. District Judge]

Before

Gelpí, Hamilton,** and Aframe,
Circuit Judges.

Warren V. Norred, with whom Norred Law, PLLC was on brief,
for appellant.

Christopher Paul Anderson, Attorney, Environment and Natural
Resources Division, U.S. Department of Justice, with whom Adam
R.F. Gustafson, Acting Assistant Attorney General, Shari Howard
and Robert P. Stockman, Attorneys, Environment and Natural
Resources Division, U.S. Department of Justice, Jori
Reilly-Diakun, Adrienne Trivedi, Kai Hill, and Robert W. Caplan,
Attorneys, U.S. Environmental Protection Agency, were on brief,
for appellees.

* Pursuant to Fed. R. App. P. 43(c)(2), Administrator Lee M.
Zeldin has been substituted for former Administrator of the U.S.
Environmental Protection Agency Michael Stanley Regan as appellee.

** Of the Seventh Circuit, sitting by designation.

September 18, 2026

GELPÍ, Circuit Judge. In May 2023, the Environmental Protection Agency ("EPA") issued a Stop Sale, Use, or Removal Order ("Stop Order") prohibiting Appellant Berkey International, LLC ("Berkey") from distributing or selling certain water filters that contain silver, a known pesticide. Berkey sought a preliminary injunction barring enforcement of the Stop Order, claiming that the EPA's action was arbitrary and capricious, and contrary to law under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, because it had no "reason to believe" that the water filters violated the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or the "Act"), 7 U.S.C. § 136, et seq. Berkey now challenges the denial of its motion for preliminary injunctive relief. Because Berkey failed to substantiate its claim that the silver is not intended for a pesticidal purpose -- and thus, its tandem claim that the water filters are exempt from FIFRA's requirements -- we conclude that Berkey has not shown a likelihood of success on its APA claims. Therefore, we affirm the district court's order.

I.

A. Legal Framework

We begin with an overview of the regulatory regime underpinning this case. FIFRA governs the registration, labeling, distribution, sale, and use of pesticides in the United States, 7 U.S.C. § 136, et seq. A pesticide is "any substance or mixture of

substances intended for preventing, destroying, repelling, or mitigating any pest," id. § 136(u), including "[p]esticide product[s]," which are pesticides "in the particular form (including composition, packaging, and labeling) in which the pesticide . . . is distributed or sold," 40 C.F.R. § 152.3. Pesticide products include "any physical apparatus used to deliver or apply the pesticide if distributed or sold with the pesticide." Id. In other words, "[i]f a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA." U.S. Env't Prot. Agency, Pesticide Registration Manual: Chapter 13 - Devices 2 (2025) (hereinafter Pest. Reg'n Man.).¹ Regulations further specify when "[a] substance is considered to be intended for a pesticidal purpose." 40 C.F.R. § 152.15. For purposes of this case, that includes when the "person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance . . . can or should be used as a pesticide." Id. § 152.15(a)(1).

¹ The Pesticide Registration Manual is available at <https://www.epa.gov/system/files/documents/2021-08/pesticide-registration-manual-chapter-13.pdf> [<https://perma.cc/V9PE-3HJM>].

Under FIFRA, it is "unlawful", among other things, "to distribute or sell" a pesticide or pesticide product "that is not registered" with the EPA, 7 U.S.C. § 136j(a)(1)(A), or that is "misbranded," id. § 136j(a)(1)(E). A pesticide is misbranded, as relevant in this case, if "its label does not bear the registration number assigned" under the Act. Id. § 136(q)(1)(D). Under FIFRA's regime, pesticide manufacturers must seek pre-authorization to distribute or sell pesticides, see id. § 136a, and "have a continuing obligation to adhere to FIFRA's labeling requirements," Bates v. Dow Agrosciences LLC, 544 U.S. 431, 438 (2005). See also 7 U.S.C. § 136j(a)(1)(E).

There are also some exceptions. Pesticidal "devices" are exempt from FIFRA's registration requirement, 40 C.F.R. § 152.500, and "treated articles" are exempt from all FIFRA regulations, id. § 152.25(a). If an entity is not sure whether its products must be registered, or if its products qualify as devices or treated articles, it may request a formal determination from the EPA as to the regulatory classification of those products. See Pest. Reg'n Man. 3 (noting that manufacturers who "are uncertain about whether [their] product requires EPA registration as a pesticide . . . may request a determination from EPA . . . as to whether [their] product is considered a pesticidal device"); 7 U.S.C. § 136w-8(b)(3)(B), at table 19 (listing fee category "M009" for applicant-initiated, non-FIFRA regulated determinations); U.S.

Env't Prot. Agency, M009 PRIA Fee Category (Apr. 29, 2026) (indicating that an entity may "voluntar[ily] request that EPA determine . . . whether and how a product is regulated under FIFRA").²

The EPA has authority to enforce FIFRA if "there is reason to believe on the basis of inspection or tests that [a] pesticide or device is in violation of any of the provisions of" FIFRA, or if the pesticide or device "has been or is intended to be distributed or sold in violation of any such provisions." 7 U.S.C. § 136k(a). The EPA's enforcement mechanisms include the issuance of a Stop Sale, Use, or Removal Order, which, as the name implies, bars the sale, use, or removal of a "pesticide or device described in the order except in accordance with the provisions of the order."³ Id.

B. Factual Background

Berkey is a Puerto Rico limited liability company that manufactures mechanical water filters. The water filters at issue in this case, the Black Berkey Filters, use "a tortuous maze of

² The M009 PRIA Fee Category is available at <https://www.epa.gov/pria-fees/m009-pria-fee-category> [<https://perma.cc/8CGC-BQXS>].

³ Other enforcement mechanisms include seizures and civil penalties. See 7 U.S.C. §§ 136k, 136l; U.S. Env't Prot. Agency, FIFRA Enforcement Response Policy 5 (2009), <https://www.epa.gov/sites/default/files/documents/fifra-erp1209.pdf> [<https://perma.cc/YD22-PV49>].

micropores to separate pests from the effluent water." Black Berkey Filters are a component of numerous other Berkey products, such as Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, and others. Black Berkey Filters also contain silver, which is a recognized pesticide.⁴ Despite FIFRA's general registration and other regulatory requirements, for many years Berkey manufactured and sold these water filters without registering them with the EPA.

In April 2022, the EPA inspected an inbound shipment of Berkey products at customs in Denver, Colorado. The shipment belonged to New Millenium Concepts, Ltd. ("NMCL"), which is licensed to manufacture and sell Berkey products. On May 4, 2022, Defendant-Appellee Christine Tokarz issued a compliance advisory letter to NMCL.⁵ The letter stated, first, that producing a pesticide device in an establishment that is not registered with the EPA violates FIFRA § 12(a)(2)(L), codified at 7 U.S.C. § 136j(a)(2)(L). The letter then quoted "a partial list of

⁴ Silver was first registered as a pesticide in 1954. U.S. Env't Prot. Agency, R.E.D. Facts Silver 2 (June 1993) <https://archive.epa.gov/pesticides/reregistration/web/pdf/4082fact.pdf> [<https://perma.cc/P5Y4-FSL3>]. In 2007, silver was reregistered as a pesticide. U.S. Env't Prot. Agency, Pesticides that have Completed Product Reregistration (Jan. 29, 2026), <https://www.epa.gov/pesticide-reevaluation/pesticides-have-completed-product-reregistration> [<https://perma.cc/4X5M-7T97>].

⁵ Tokarz issued the letter in her capacity as FIFRA Inspector, Toxics and Pesticides Enforcement Section, Enforcement and Compliance Assurance Division, at the EPA.

potential false or misleading pesticidal claims" found on www.berkeywater.com, including this one:

Berkey® Systems equipped with Black Berkey® Purification Elements remove up to 99.999% of viruses and 99.9999% of pathogenic bacteria, while also removing or dramatically reducing protozoa, trihalomethanes, inorganic materials, heavy metals, pharmaceuticals, pesticides, VOCs, petroleum products, perfluorinated chemicals, rust, silt, sediment and even radiologicals. (<https://www.berkeywater.com/travel-berkey-system-1-5-gal/>)

Based on these claims, the letter advised NMCL that it "may be in violation of FIFRA [§] 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F), for distributing a device that is misbranded."

Seven months after issuing the advisory letter to NMCL, in November 2022, the EPA inspected the facilities of James Enterprise, Inc., doing business as Berkey Filters. During the inspection, the EPA observed Berkey-brand filters, including the Black Berkey Filter and other filtration products containing it, stored for distribution and sale. The labels on the Black Berkey Filters included the following language:

Black Berkey Purification Elements:
VIRUSES: >99.999%
PATHOGENIC BACTERIA (AND SURROGATES)
>99.9999% -Exceeds Purification Standard (Log
6): Bacillus anthracis (Anthrax Surrogate)

The EPA also observed claims on the website www.berkeyfilters.com, including that "Black Berkey water filter elements removed 100% of the pathogens" in testing, and that another product was "designed

to remove and/or dramatically reduce a vast array of health-threatening contaminants." And a brochure for another water filter claimed to remove "toxic chemicals" and absorb "pollutants into the filter such as aluminum, cadmium, chromium, copper, lead, mercury, and other dangerous heavy metals."

Based on these statements, among others, and the inspection, Defendant-Appellee David Cobb⁶ issued a Stop Sale, Use, or Removal Order on December 27, 2022, ordering James Enterprise to immediately stop selling, using, or removing Black Berkey Filters (and filters that contain them). The order concluded that the filters "are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to [§] 2(h) of FIFRA, 7 U.S.C. § 136(u)"; were not registered with the EPA; did not "bear a registration number assigned . . . to the establishment in which the products were produced, making them misbranded" under FIFRA, id. § 136(q)(1)(D); and that James Enterprise "distributed or sold, and continues to distribute or sell," the unregistered and misbranded pesticides in violation of FIFRA, id. § 136j(a)(1)(A), (E).

⁶ Cobb issued the order in his capacity as Section Supervisor, Toxics and Pesticides Enforcement Section, Enforcement and Compliance Assurance Division, at the EPA.

Between February and May 2023, the EPA issued six additional Stop Sale, Use, or Removal Orders against manufacturers and distributors of Berkey filters, including Berkey itself. The Berkey Stop Order was issued on May 8, 2023. As the basis for the order, the EPA cited the November 2022 inspection of James Enterprise and the various claims made on the filter labels, www.berkeyfilters.com, and <https://berkey-store.com>. As in the James Enterprise order, the EPA concluded that Black Berkey Filters are "pesticides" under FIFRA which (a) were not registered with the EPA and (b) were misbranded, as they did not bear the registration number assigned to the facility in which they were produced. The Stop Order prohibited Berkey from selling, using, or removing Black Berkey Filters and other filters that contained them, and required Berkey to provide an initial, written "accounting" of all such products, followed by an updated accounting every thirty days until it no longer owned or controlled Black Berkey Filter products.

C. Procedural History

In March 2024, Berkey sued the EPA, the EPA Administrator, and Tokarz and Cobb in their official capacities, in the United States District Court for the District of Puerto Rico. Berkey claimed that the Stop Orders violate the APA, 5 U.S.C. § 706, and the Fifth, Ninth, and Tenth Amendments of the

U.S. Constitution. Berkey also requested preliminary injunctive relief against enforcement of the Stop Order.

Following a preliminary injunction hearing, submission of the administrative record ("AR"), extensive briefing, and a renewed motion for a preliminary injunction, the district court ruled on various evidentiary objections, made findings of fact, and ultimately denied Berkey's motions for injunctive relief in June 2024. Berkey moved for reconsideration, which the district court denied. Berkey then filed this interlocutory appeal.

II.⁷

We review the district court's order denying preliminary injunctive relief for abuse of discretion. Becky's Broncos, LLC v. Town of Nantucket, 138 F.4th 73, 77-78 (1st Cir. 2025). Under abuse-of-discretion review, we examine factual findings for clear error and legal questions de novo. Id. at 78 (quoting Russomano v. Novo Nordisk Inc., 960 F.3d 48, 53 (1st Cir. 2020)).

To obtain a preliminary injunction, Berkey must establish (1) "that [it] is likely to succeed on the merits," (2) "that [it] is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in [its] favor," and (4) "that an injunction is in the public

⁷ The district court had jurisdiction pursuant to 7 U.S.C. § 136n(a), allowing for review of "final actions" by the EPA Administrator that do not "follow a hearing." We have jurisdiction pursuant to 28 U.S.C. § 1292(a)(1).

interest." New York v. Trump, 171 F. 4th 1, 15 (1st Cir. 2026) (quoting Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)). The first of these factors is critical, as a movant who cannot show a likelihood of success on the merits cannot obtain a preliminary injunction. See Akebia Therapeutics, Inc. v. Azar, 976 F.3d 86, 92 (1st Cir. 2020) (describing likelihood of success "as the 'sine qua non' of the preliminary injunction inquiry"). Hence, we will start by considering whether Berkey has shown a likelihood of success on the merits.

A. Likelihood of Success

To establish a likelihood of success on the merits, Berkey must show that the EPA had no "reason to believe on the basis of inspection or tests" that Berkey's water filters were unregistered and misbranded pesticidal products. 7 U.S.C. § 136k(a). Berkey broadly claims that the EPA had no basis in the AR, or any legal reason, to believe the filters violate FIFRA, and so issuing the Stop Order was contrary to law and exceeded the EPA's statutory authority. Berkey also asserts a violation of the APA's notice-and-comment procedures, and claims the EPA violated due process by issuing the Stop Order without notice or an opportunity to be heard. We now consider each claim in turn.

1. APA Claim -- Contrary to Law

The APA governs our review of the EPA's actions under FIFRA. See Campanale & Sons, Inc. v. Evans, 311 F.3d 109, 116

(1st Cir. 2002) (citing Dubois v. U.S. Dep't of Agric., 102 F.3d 1273, 1284 (1st Cir. 1996)). Pursuant to the APA, we will only disturb agency action that was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Accordingly, we will not set aside the Stop Order unless the EPA:

. . . has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Housatonic River Initiative v. EPA, 75 F.4th 248, 269 (1st Cir. 2023) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983)). This standard is highly deferential, and "the scientific and technical nature of the EPA's decision-making increases our level of deference." City of Taunton v. EPA, 895 F.3d 120, 126 (1st Cir. 2018) (citation modified).

Berkey argues that the EPA's issuance of the Stop Order was contrary to law, and arbitrary and capricious, see 7 U.S.C. § 706, because the EPA "had no legal reason" or "basis in the administrative record" to believe Berkey violated FIFRA. Berkey admits that silver is a pesticide, and that its filters contain silver. Berkey also admits that it has not registered its filters with the EPA. But Berkey contends it did not have to do so because

the silver in the filters does not serve a pesticidal purpose. Rather, Berkey claims its filters are "devices" exempt from registration as pesticides, see 40 C.F.R. § 152.500, and have been recognized as such "for over twenty-five years." Berkey further contends the water filters are also "treated articles" exempt from all FIFRA regulation, see id. § 152.25(a).

We begin with the "device" exemption. The Code of Federal Regulations states, in relevant part:

A device is defined as any instrument or contrivance . . . intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals).

40 C.F.R. § 152.500(a). Devices are "not required to be registered under FIFRA sec. 3." Id. § 152.500(b). In asserting that its water filters are devices, Berkey cites a notice in the Federal Register, which provides that:

[I]f an article uses physical or mechanical means to trap, destroy, repe[l], or mitigate any plant or animal life declared to be a pest . . . , it is considered to be a device. If the article incorporates a substance or mixture of substances intended to prevent, destroy, repe[l], or mitigate any pest, it is considered to be a pesticide.

Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065, 51065 (Nov. 19, 1976). Berkey asserts that the silver in its water filters does

not chemically disinfect or purify the water. Rather, according to Berkey, the silver protects the filters, and the filters in turn use "a microscopic tortuous maze that traps pests" to clean the water. Berkey compares this process to the function of an air conditioning filter or a mosquito net.

The EPA counters that when a device also incorporates a pesticidal substance, as here, it may still be considered a pesticidal product that is regulated as a pesticide. See 40 C.F.R. § 152.3 (defining "pesticide product"); Pest. Reg'n Man. 2 ("If a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA [§] 3."). Indeed, regulations in place since the 1970s provide that devices which are not subject to regulation include water filters, "except those containing substances," i.e., pesticidal substances like silver. Regulations for the Enforcement of FIFRA, 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added); Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065, 51065 (Nov. 19, 1976). Thus, although the water filters (the "article") use a maze (a "physical or mechanical means") to trap pests, because the filters "incorporate[]" silver, the question becomes whether the silver is

"intended to prevent, destroy, repel, or mitigate any pest." Pest. Reg'n Man. 2.

Because FIFRA is a pre-authorization statute which places the onus for compliance on manufacturers and distributors, the burden of answering this question in the negative falls on Berkey. See 7 U.S.C. § 136a (providing for registration of pesticides); id. § 136j(a)(1)(A), (E) (providing that, in general, it is "unlawful," among other things, "to distribute or sell" an unregistered pesticide or misbranded device). See also Bates, 544 U.S. at 438 (noting that "manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements"); Stearns Elec. Paste Co. v. EPA, 461 F.2d 293, 304 (7th Cir. 1972) ("The 1964 amendment to FIFRA was clearly and specifically intended to shift the burden of proof from the [Administrator] to the registrant."). But in asserting the silver is solely intended to protect the filters, Berkey has only cited to the declaration of its President, James Shepherd. As articulated by the Third Circuit decades ago, a "manufacturer or distributor cannot avoid the reach of [FIFRA] by pointing to its own subjective intent that a product ha[s] a given use." N. Jonas & Co. v. EPA, 666 F.2d 829, 833 (3d. Cir. 1981). Berkey's failure to substantiate Shepherd's declaration dooms its claim to the device exemption.⁸

⁸ Berkey's assertion that its water filters have been recognized as devices for decades is completely unsupported by the

As a final point, even if the water filters were classified as devices, that would only get Berkey past FIFRA's registration requirement, as devices are still subject to FIFRA's prohibition against misbranding. 40 C.F.R. § 152.500(b)(1). And per the Stop Order, Berkey's filters did not "bear a registration number assigned under FIFRA [§] 7 to the establishment in which the products were produced, making them misbranded pursuant to [§] 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D)."

We now turn to Berkey's assertion that its water filters are "treated articles." The Code of Federal Regulations defines treated articles as:

An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.

40 C.F.R. § 152.25(a). Thus, for Berkey's water filters to be defined as a treated article, (1) the purpose of the silver must be "to protect the article or substance itself," and (2) the silver must be "registered for such use." Id. Treated articles are "exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified." Id. § 152.25.

record. It appears instead that Berkey has construed the EPA's prior lack of enforcement as tacit recognition.

With respect to the first prong, the purpose of the pesticide, we briefly cover much of the same ground as with Berkey's device argument. Berkey claims that the intended and sole purpose of the silver is to protect the water filters, and that the EPA failed to so recognize. But again, the only support for that argument is the declaration of Berkey's President, which was provided for purposes of this litigation after the EPA issued the Stop Order. Further, the EPA counters that it did consider whether the filters fell under the treated article exemption before issuing the Stop Order, but "was unable to determine, based on the information available at the time, whether the exemption was applicable." In fact, the EPA claims that it "still cannot verify that the registered pesticide that Berkey attests is in the Berkey water filters . . . is being used consistent with its registration." (Emphasis added.) Given Berkey's obligation to comply with FIFRA's regime, as well as its burden to show a likelihood of success to obtain a preliminary injunction, that declaration is, once again, not enough to get Berkey to the proverbial finish line.

As to the second requirement, the silver contained in the water filters must be registered for the non-pesticidal use. 40 C.F.R. § 152.25(a). Tellingly, while Berkey alleges that its filters "incorporate[d] a registered antimicrobial pesticide containing silver," it has not provided any citation to the AR in

support of this claim. (Emphasis added.) Rather, Berkey again cites to the declaration of its President.⁹ And, again, the burden was on Berkey to demonstrate compliance.¹⁰ The EPA claims it was "unable to verify" that the silver was registered to protect water filters, or that it was "not intended for pesticidal purposes beyond protecting the article itself." We thus conclude that Berkey has not shown the EPA lacked "reason to believe" that the water filters were pesticidal products at the time that it issued the Stop Order. 7 U.S.C. § 136k(a).

We turn to Berkey's contention that the AR offers no basis to support the EPA's determination that the water filters are pesticides that violate FIFRA. We disagree. Beyond the obvious -- that the filters incorporate silver -- the Stop Order cited the inspection of James Enterprise and pesticidal claims made on Black Berkey Filter labels and on the websites www.berkeyfilters.com and <https://berkey-store.com>.¹¹ Still,

⁹ If the silver was registered for purposes of the treated article exemption, Berkey could have moved to supplement the AR with proof of registration. See Housatonic River Initiative v. EPA, 75 F.4th 248, 278-79 (1st Cir. 2023) (discussing exceptions to the general rule against supplementing an AR). Although Berkey moved to supplement the AR in August 2024, it did not include any such evidence in the request.

¹⁰ According to the EPA, Berkey never requested a "formal determination" that its water filters qualify for this exemption, which it may do under FIFRA. See 7 U.S.C. § 136w-8(b)(3)(B), at table 19 ("M009"). The district court made this finding below, and Berkey has not disputed it on appeal.

¹¹ Recall, a substance is "considered to be intended for a

Berkey throws numerous arguments at the wall. For example, it asserts that the EPA "never visited . . . before shutting [Berkey] down," and that the EPA's "agents were working with Berkey on changes to its packaging and advertising, which would bring it into compliance." These arguments, however, do not bear on the legal analysis under FIFRA's regime.¹²

To sum up, Berkey's water filters contained silver, a known pesticide, and when the EPA investigated it, Berkey did not meet its obligation under FIFRA to show that the filters fell under a device or treated article exemption. The EPA thus had "reason to believe" that Berkey was distributing unregistered and misbranded pesticidal products in violation of the Act. 7 U.S.C. § 136k(a). On this record, we conclude that the EPA did not act arbitrarily and capriciously, or contrary to law, when it issued the Stop Order, and that Berkey has failed to show a likelihood of

pesticidal purpose" if the "person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance . . . can or should be used as a pesticide." 40 C.F.R. § 152.15(a)(1). Here, various distributors claimed, among other things, that Berkey-brand filters remove "up to 99.999% of viruses and 99.9999% of pathogenic bacteria," and "100% of the pathogens."

¹² Berkey also claims the district court abused its discretion by failing to "consider the lack of inspection data" or "examine EPA inspection data." But Berkey never explains why it believes the district court did not review the relevant part of the AR. Because this argument is undeveloped, it is waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

success on the merits of this claim. See Marasco & Nesselbush, LLP v. Collins, 6 F.4th 150, 172 (1st Cir. 2021) ("[C]ourts should uphold an agency determination if it is 'supported by any rational view of the record.'" (quoting Atieh v. Riordan, 797 F.3d 135, 138 (1st Cir. 2015))).

2. APA Claim -- Notice and Comment

Next, Berkey argues that the EPA improperly relied on nonbinding guidance, Pesticide Registration ("PR") Notice 2000-1, in issuing the Stop Order because the Notice "states that if one makes pesticidal claims regarding a treated article, it loses the . . . exemption entirely." Berkey thus argues that since the treated article regulation, 40 C.F.R. § 152.25(a), does not itself forbid pesticidal claims, the EPA must have relied on PR Notice 2000-1 as a substantive rule without going through the notice-and-comment rulemaking procedures required by the APA. See 5 U.S.C. § 553.

This argument, however, ignores other regulatory authority at 40 C.F.R. § 152.15, which pertains to "[p]esticide products required to be registered." Cf. Monsanto Co. v. Durnell, 146 S. Ct. 2001, 2011 (2026) (noting that "relevant labeling 'requirements'" include "'any relevant EPA regulations that give content to FIFRA's misbranding standards'" (quoting Bates, 544 U.S. at 453)). Section 152.15 states that a "substance is considered to be intended for a pesticidal purpose" when the

"person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance . . . can or should be used as a pesticide." Id. § 152.15(a)(1). Berkey's manufacturers and distributors did just that. See supra Section I.B and note 11. We thus conclude that Berkey has also failed to show a likelihood of success on the merits of this claim.

3. Fifth Amendment Claim -- Due Process

Finally, Berkey argues that the EPA violated Berkey's Fifth Amendment due process rights by not providing notice or an opportunity to be heard before issuing the Stop Order. The EPA responds, first, that Berkey waived this argument by not pressing it in the preliminary injunction proceedings, and second, that it fails on the merits in any event. In the district court, Berkey "neither briefed nor argued" its notice-and-opportunity claim "in any depth."¹³ 3137, LLC v. Town of Harwich, 126 F.4th 1, 13 n.7 (1st Cir. 2025). That failure precludes our review because "a

¹³ In the proceedings below, Berkey asserted a Fifth Amendment due process claim in its complaint, which was also its initial motion for a preliminary injunction. Berkey's memorandum in support of the motion, however, did not make any argument in support of that claim, and merely asked for a declaratory judgment that the EPA had violated Berkey's due process rights. The only due process arguments by Berkey surfaced in its reply brief in support of the initial motion, and those arguments largely overlapped with its notice-and-comment claim. Finally, when Berkey filed a renewed motion for a preliminary injunction, it failed to mention the due process claim entirely.

litigant has an obligation to spell out its arguments squarely and distinctly." Harriman v. Hancock Cnty., 627 F.3d 22, 28 (1st Cir. 2010) (citation modified). Litigants also have an obligation to spell out those arguments in a "timely" manner. Brox v. Woods Hole, 164 F.4th 37, 43 (1st Cir. 2026) (quoting Iverson v. City of Boston, 452 F.3d 94, 102 (1st Cir. 2006)) (affirming the district court's waiver finding where an argument was only raised in a reply brief). Because Berkey failed to do so, we conclude that its Fifth Amendment claim is waived, and we do not reach the merits.

B. Remaining Preliminary Injunction Factors

Because Berkey has not established that it is likely to succeed on the merits of any of its claims, the "most important" element in the preliminary injunction calculus, Akebia Therapeutics, Inc., 976 F.3d at 92, "we need not address the remaining preliminary injunction factors," Brox, 164 F.4th at 51.

III.

For the foregoing reasons, the order of the district court is **affirmed**.